

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 16 SEP 2005

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Applicant's or agent's file reference JWJ01059WO		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/GB2004/003088		International filing date (day/month/year) 15.07.2004		Priority date (day/month/year) 15.07.2003
International Patent Classification (IPC) or national classification and IPC G01N33/543, G01N21/55				
Applicant DENSHAM, Daniel Henry				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 15.02.2005		Date of completion of this report 15.09.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Diez Schlereth, D Telephone No. +49 89 2399-7488		

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**INTERNATIONAL PRELIMINARY REPORT
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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-5 as originally filed

Claims, Numbers

1-14 received on 18.05.2005 with letter of 16.05.2005

Drawings, Sheets

1/1 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 13-14

because:

☒ the said international application, or the said claims Nos. 13-14 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2,9,11
	No: Claims	1,3-8,10,12-14
Inventive step (IS)	Yes: Claims	2
	No: Claims	1,3-14
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	13-14

2. Citations and explanations (Rule 70.7):

see separate sheet

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item III

The scope of present claims 13-14 does not explicitly exclude embodiments relating to subject-matter related to diagnostic/detection methods that are carried out "in vivo" involving the treatment, of the living human/animal body by implantation of the sensing elements by surgery. The referred subject-matter is considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT and consequently, no report will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34 (4) (a) (I) PCT).

item V

1.) Reference is made to the following documents:

- D1: A. J. Haes & R. P. Van Duyne (2002) J. Am. Chem. Soc. 124, 10596-10604
- D2: S.-F. Cheng & L.-K. Chau (2003) Anal. Chem. 75, 16-21
- D3: L. Andrew Lyon et al (1999) Sensors & Actuators B 54, 118-124
- D4: L. He et al (2000) J. Am. Chem. Soc. 122, 9071-9077
- D5: WO-A-01/09388
- D6: WO-A-99/05315
- D7: WO-A-01/20295
- D8: N. Lochner et al (2003) Eur. J. Pharma. Biopharma. 56, 469-477

2.) The subject-matter of claims 1, 3-8, 10 and 12-14 is not novel within the sense of Art. 33 (2) PCT, for the following reasons:

D1 discloses a localized surface plasmon resonance nanobiosensor comprising a monolayer (a matrix) of biotinylated silver nanoparticles covering a glass surface (see figs. 1-5; abstract). D1 anticipates the subject-matter of claims 1, 3, 5, 7-8, 10 and 12-14.

D2 discloses a fiber-optic evanescent-wave sensor comprising an unclad portion modified with a self-assembled monolayer of colloidal gold particles (p. 16-17). D2 anticipates the subject-matter of claims 1, 3-7, 10 and 12-14.

D3-D5 discloses the use of colloidal gold particles for the enhancement of SPR-based

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sandwich assays. In this assay, the binding event is detected by a large shift in plasmon angle caused by aggregation of nanoparticle-labels on the sensor surface (D3, p. 118-119; D4, p. 9072-9073 and D5, examples 1-3). D3-D5 anticipate the subject-matter of claims 1, 3-8, 10 and 12-14.

3.) The subject-matter of dependent claims 9 and 11 (partially, as referring to claim 1) is considered to be novel (Art. 33 (2) PCT), but not inventive within the sense of Art. 33 (3) PCT because it relates to obvious alternatives of the sensor element of claim 1, which fall within the routine practice in this technical field and which do not seem to result in any unexpected technical effect.

4.) The subject-matter of claims 2 (complete) and 9, 11 (partially, as dependent thereon) is considered to be novel and inventive within the sense of Art. 33 (2) and (3) PCT, for the following reasons:

The sensing element of claim 2 differs from that of D1 (closest state of the art) in that it comprises multiple particles that are stacked within a matrix.

The devices of D1-D3 comprise matrices which are formed by deposition of a monolayer or a sub-monolayer of metallic particles on a solid support (see D1, fig. 1; D2, p. 17, l. col.; D3, p. 118, r. col.). Analogous arguments apply for the devices of D4-D5, in which the particles are used for labeling a binding partner (see D4, p. 9073, l. col. and D5, p. 4, l. 5-7). The devices of D6-D7 (see figures) do not comprise any particulate sensing element.

The skilled person equipped with the teaching of D1-D7 would not be motivated to modify the sensing element of D1 by having a matrix comprising multiple particles stacked therein, as claimed in claims 2 (and 9, 11 as dependent thereon) for improving the sensitivity of the sensor. A matrix comprising multiple discrete particles stacked therein, wherein the particles are capable of supporting surface electromagnetic waves generates an evanescent field that extends much deeper into the solution, thereby "sensing" a larger amount of sample, which results in an increase of the sensor signal.

5.) D8 discloses the use of microplate substrates coated with silver nanoparticles for the enhancement of the signal in fluorescence-based immunoassays (see fig. 1). This document

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may be relevant when the application enters the regional phase in the case of an invalid priority date.

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